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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,071	03/24/2000	Stephen Pacetti	1225.001US1	2171

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EXAMINER
BUI, VY Q

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/534,071	PACETTI ET AL.	
	Examiner	Art Unit	
	Vy Q. Bui	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *8,10-12,22-28,30-33,36,39 and 52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,13-21,29,34,35,37,38 and 40-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2, 3, 4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21, 29-52, drawn to a radiopaque stent and a method of using the radiopaque stent, classified in class 623, subclass 1.15.

II. Claims 22-28, drawn to a method of making a stent, classified in class 156, subclass 180.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed, such as injection molding (claim 28), can be used to make other and materially different product, such as an auto part or a hand tool.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species having distinct mechanical structures of the claimed invention:

Species A: Fig. 5, a laser cut stent with undulating pattern.

Species B: Fig. 7, a stent with a solid radiopaque tube.

Species C: Fig. 8, a backbone-shaped stent.

Species D: Fig. 9, a coiled stent.

Species E: Fig. 10, a ratcheted stent.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with the Applicants' Attorney, Mr. Juo, on 12/12/2002 a provisional election was made with traverse to prosecute the invention of Fig. 5, claims 1-7, 9, 13-21, 29, 34-35, 37-38, and 40-51. Affirmation of this election must be made by applicant in replying to this "Office Action". Claim 8 (a solid radiopaque tube stent), claim 10 (a coiled stent), claim 11 (a racheted stent), claim 12 (a backbone-shaped stent), claims 22-28 (method of making a stent), claims 30-33 and 52 (a wire stent), claim 36 (elected species II is not self expandable stent), claim 39 (a Co-Cr-Ni stent having molybdenum: non-elected species I indicated in previous papers) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-2, 5-7, 9, 13-16, 19-21, 29, 34-35, 37-38, 43, 45 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by FARIABI (6,419,693).

As to claims 1-2, 5-7, 9, 13, 19-21, 34-35, 37 and 51, FARIABI (Fig. 5-7; abstract, lines 5-10; claim 1) discloses a radiopaque stent 50 of Cobalt-Nickel-Chrome (Co-Ni-Cr) alloy comprising a radiopaque material such as tungsten (W). Stent 50 comprises tubular main body defining undulating pattern with holes. Stent 50 is carried by catheter 51 to be deployed in blood vessel 57 and expandable by balloon 54 (Fig. 6).

As to claims 14-16, 43 and 45, FARIABI (claim 1) discloses a stent of 5%-35% Cr, 0%-20% W and 2%-40% Ni.

As to claim 29, FARIABI (Fig. 5-7) discloses a method of deploying radiopaque Co-Ni-Cr stent 50 to a lesion site 56 in blood vessel 57 as recited in the claim.

As to claim 38, the radiopaque material tungsten (W) in FARIABI stent has an atomic number of 74.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 3-4, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over FARIABI (6,419,693).

As to claims 3-4, FARIABI discloses substantially all structural limitations as recited in the claim, except for an unexpanded outside diameter, a second expanded diameter, and a wall thickness as recited in the claims. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make FARIABI stent to have the dimensions as recited in the claims, as this configuration would be within level of one of ordinary skill in the art to determine according to the size of a blood vessel, the size of a deployment catheter and the required radial strength of a stent.

As to claim 17, FARIABI discloses substantially all structural limitations as recited in the claim, except for the stent main body is visible but does not obscure the underlying vessel morphology when subjected to imaging. It would have been obvious to one of ordinary skill in the art at the time the invention was made to arrange the undulating pattern of FARIABI stent to be strong enough to support the blood vessel and thick enough such that the stent main body is visible as recited in the claim, as this configuration of the FARIABI stent would facilitate observing the stent and the blood vessel during the stent deployment. In addition, the stent of Co-Ni-Cr alloy such as the L605 alloy as specified in the elected species (page 11, present invention) is well known

for the radio opaqueness and has been known to be used to make a radio opaque stent (please, see WO 00/54704, which has a equivalent U.S. application 09/270,403 filed on March 16, 1999 prior to the filing date of this present invention).

As to claims 40-42, 44, 46-50, FARIABI discloses substantially all structural limitations as recited in the claim, except for the other characteristics as recited I the claims. However, the alloy as recited in the claim is identified as a well-known L605 alloy, which has been known to be used to make a radiopaque stent (please, see WO 00/54704, which has a equivalent U.S. application 09/270,403 filed on March 16, 1999). It would have been obvious to one of ordinary skill in the art to make FARIABI stent from a L605 alloy as this well known material L605 has been recognized as a suitable ~~radio-opaque~~ m- strength material to make a radio opaque stent strong enough for support a blood vessel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2708 for regular communications and 703-308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

VQB

December 15, 2002.